SEP - 8 2011

510(k) Summary

Optovue, Incorporated

RTVue CAM with Corneal Power Measurement

This 510(k) summary for the RTVue CAM with Corneal Power Measurment is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:

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Device Information

Classification:

Class II

Trade Name:

RTVue CAM with Corneal Power Upgrade

Common Name:

Optical Coherence Tomography (OCT)

Classification Name:

Ophthalmoscope, a-c powered (21 CFR§ 886.1570)

Predicate Devices

(1) RTVue/CAM Module (K071250)-manufactured by Optovue, Inc.
(2) Pentacam Scheimpflug Camera (K030719) – manufactured by Oculus

Intended Use

The CA, an auxiliary lens adapter, when used in conjunction with RTVue, is indicated for *in vivo* imaging and measurement of the cornea and the other ocular structures of the anterior segment of the eye, including pachymetry and corneal power .

Device Description

The already cleared (K071250) RTVue CA Module (CAM) is an instrument based on Fourier-Domain Optical Coherence Tomography (OCT) for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye with US FDA 510(k) clearance (K071250) in 2007. The RTVue CAM has been used in clinical practice for imaging the cornea, measuring corneal thickness, and visualizing the anterior segment angle. The RTVue CAM device uses the same Optical Coherence Tomography (OCT) technology that was previously cleared by FDA (K101505). The CAM adapter gives the user an option to use the RTVue device as previously approved for retina scans, or to use it for cornea and anterior eye scans. Aside from the CAM auxiliary attachment, the RTVue is virtually unchanged for the CAM use except the CAM software module provides for menu selections in the graphical user interface, which are selected by the operator to label corresponding corneal landmarks instead of those of the retina. The system scans a beam into patient's eye and uses a low coherence interferometer to measure the reflectivity of the ocular tissue. The cross-sectional ocular tissue structure is composed of sequence of A-scans. The RTVue has a traditional patient and instrumentinterface like most ophthalmic devices. The device is mounted on a motorized patient table. The patient will rest their head on the forehead and chin rest. The operator uses joystick to align the device to patient's eye. The computer has a graphic user interface for acquiring, analyzing and displaying the acquired image. The RTVue image acquisition speed and image resolution remain the same when used in conjunction with CAM

Upgraded Software for CAM Corneal PowerMeasurements

RTVue CAM is already cleared (K071250) for corneal thickness measurement (pachymetry measurement). In addition to the corneal thickness, the anterior and posterior corneal surface curvatures can also be measured from the cross-sectional image of the cornea acquired with RTVue CAM; from these measurements, net corneal power can be calculated using a simple thick lens formula. RTVue CAM with Corneal Power requires only a software upgrade to RTVue CAM and a calibration for corneal power measurement using a calibration sphere with prespecified radius of curvature. The upgrade and calibration can be performed at a customer site by a qualified customer support/service personnel. There is no hardware change to the RTVue CAM system.

Once system is upgraded for Cornela Power measurement, the software will prompt user to perform weekly validation test with the same calibration sphere and its value compared with initial calibration value to verify system stability. The limits of the acceptable difference is set to ±0.25D; if exceeded, the software would not allow corneal power measurement until the system passes the validation test. A warning message is displayed on screen with instruetions for further action.

Corneal power is one of the key input parameters for IOL power calculation in cataract surgery. In clinical practice, corneal power is commonly measured by manual or automated keratometry or by simulated keratometry

(Sim-K) from Placido-ring corneal topographers. Corneal power provided by keratometry or topography is based on measuring the anterior surface curvature of the cornea and assuming a fixed ratio of 0.883 between posterior and anterior curvature to compute the total corneal power.[3] Corneal power measurement with keratometer or topographer works well enough in normal eyes, but the assumption of fixed ratio between anterior and posterior curvature could lead to erroneous corneal power assessment in eyes with corneal pathology or eyes with prior refractive surgery for obvious reasons.[1,2,3] Therefore, direct measurement of both anterior and posterior corneal curvatures to assess true corneal refractive power is advantageous. Several technologies have been developed to assess corneal refractive power based on measurement of anterior and posterior corneal curvatures from cross-sectional corneal images, including Pentacam Scheimpflug Camera and RTVue CAM.

The RTVue CAM net corneal power is not expected to be interchangeable with keratometric corneal power measurements or Pentacam corneal power measurement using existing formulas developed for these devices for IOL power calculation.

Safety

The energy level and all safety related design of the RTVue remains the same when used in conjunction with CAM with Corneal Power Feature . The only difference is that the CAM with Corneal Power Feature allows the RTVue system to image the cornea instead of the retina. The addition of the CAM with Corneal Power Feature does not affect the system's safety; and as such, does not raise any safety issues.

Effectiveness

The validation of effectiveness of the RTVue CAM with Corneal Powerhas been analyzed in detail. The data in Section 18 of this document shows that theTest evaluation of the RTVue CAM WITH CORNEAL POWER as compared to the RTVue CAM and Pentacam Scheimpflug Camera (K030719), a predicate device to RTVue CAM for corneal refractive power assessment, the results demonstrates, both qualitatively and quantitatively substantially equivalent to the approved RTVue CAM OCT Fourier domain OCTand the approved Pentacam Scheimflug Camera.

Substantial Equivalence

The RTVue CAM with Corneal Power Measurerment is substantially equivalent to the predicate devices presented within this premarket notification with regard to intended use, operating principle, function, material, and energy source, all of which are similar.

The predicate devices are RTVue CAM and Pentacam. RTVue CAM with Corneal Power is a software upgrade to RTVue CAM, no change to operating principle, anterior segment imaging function, energe source, and indication for use. RTVue CAM with Corneal Power measures the corneal refractive power based on measuring directly the corneal anterior surface radius of curvature and the posterior surface radius of curvature based multi-meridian cross-sectional images of the cornea, which is substantially equivelnt to the method for corneal power assessment with another predicate device, Pentacam Scheimpflug Camera.

Performance Data

Tests:
Bench test data was collected and evaluated to support the intended use for the RTVue CAM-Land to demonstrate substantial equivalence to the predicate devices.

Corneal Power upgrade to RTVue CAM was performed by a qualified Optovue personnel. The upgrade may be performed in field or in the factory. Once the software is installed, the software automatically promt for corneal

power measurement calibration. To perform corneal power calibration, a ceramic ball with known curvature (the diameter is 15.875mm, and the equivalent power is 47.37D using index 1.376) is mounted on the CAM-L lens and scanned using corneal power validation protocol (details available in the installation procedure). The accuracy of the calibration is required to be ±0.25D for corneal power measurement. Once calibrated, the software automatically prompt for acceptance test (see installation instruction for details).

The acceptance test is performed with a spherical target with a different radius of curvature from that of the calibration target. The system must pass the acceptance test before the corneal power measurement feature is enabled. To ensure system is stable over time, a weekly corneal power validation test is also required. The software automatically prompt for the weekly validation test. The validation test is performed with the same calibration target (stored with the instrument). The result of the validation test is compared with initial calibration result to verify system stability. The limits of the acceptable difference is set to ±0.25D; if exceeded, the software would not allow corneal power measurement until the system passes the validation test. A warning message is displayed on screen with instruetions for further action.

To verify the accuracy of the corneal power calibration, a bench test was performed where the curvatures of four ceramic balls with different diameters were measured with RTVue CAM after corneal power calibration. The four ceramic ball diameters were 12.701mm, 13.494mm, 15.874mm and 19.049mm; 3 measurements were performed on each. The results are shown in the table below. As shown, the difference between the mean measured curvature and the ground truth for each ball is less than 0.25D. Therefore, we conclude that the calibration can effectively correct the system aberration within the measurement range of interest (note that the power in the Table is based on refractive index of 1.376, the corresponding power value based on keratometric refractive index of 1.3375 should be scaled down with a factor of 0.3375/0.376).

	Ceramic Ball 1		**Ceramic Ball 2**		**Ceramic Ball 3**		**Ceramic Ball 4**	
Truth Value	Power (D) (n=1.376)	Diameter (mm)	Power (D) (n=1.376)	Diameter (mm)	Power (D) (n=1.376)	Diameter (mm)	Power (D) (n=1.376)	Diameter (mm)
	59.2079	**12.701**	**55.7285**	**13.494**	**47.3731**	**15.875**	**39.471**	**19.049**
Scan 1	59.27133	12.6874	55.82806	13.4699	47.40758	15.8624	39.57032	19.0041
Scan 2	59.25067	12.6918	55.85877	13.4625	47.43162	15.8544	39.66517	18.9587
Scan 3	59.29819	12.6817	55.85465	13.4635	47.42144	15.8578	39.56976	19.0044
Mean	**59.2734**	**12.6870**	**55.8472**	**13.4653**	**47.4202**	**15.8582**	**39.6018**	**18.9891**
Error	**0.0655**	**-0.0140**	**0.1187**	**-0.0287**	**0.0471**	**-0.0168**	**0.1308**	**-0.0599**

Conclusion

As described in this 510(k) Summary, comprehensive testing and analyses were completed on the RTVue Cam with Corneal Power to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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SEP - 8 2011

Re: K111505
Trade/Device Name: RTVue CAM with Corneal Power Measurement
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Codes: OBO, MMQ
Dated: August 8, 2011
Received: August 10, 2011

Dear Mr. Talarico:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Statement of Indications for Use

510(k) Number (if known): K111505

Device Name: RTVue CAM with Corneal Power Measurement

Indications for Use:
The CA, an auxiliary lens adapter, when used in conjunction with RTVue, is indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye, including pachymetry and corneal power.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office~~ of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number k111505